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Public Health Ethics

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FROM THE EDITOR
To the Betterment of Public Health
Susanna Smith

Physicians' ethical obligation to the health of the public is clearly laid out in the *Principles of Medical Ethics*. Principle VII states: "a physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health."

Physicians have the opportunity to contribute to the betterment of public health more often than thay may know. This issue of *Virtual Mentor* focuses on how physicians' every day clinical decisions affect the health of the public. We present clinical encounters in which physicians are faced with situations of public health concern such as patients who are being abused or struggling to tell partners about their HIV-positive status. We examine how physicians' other ethical obligations, such as keeping patient-physician confidentiality, may conflict with their interests in protecting the public and with legal mandates. Physician choices, such as opting to practice concierge medicine or not considering cost-effectiveness in treatment decisions, may also affect public health by making health care less accessible and affordable. We offer a perspective on physician roles in curbing patient decisions that are not in the best interest of society such as refusing to have children vaccinated.

The learning objectives for this issue on public health ethics are:

- Understand how patient confidentiality may be compromised by public health reporting laws.
- Identify circumstances in which physician autonomy may conflict with public health interests and goals.
- Understand how individual medical decisions in the aggregate are public health decisions.
- Recognize how health care spending on individuals uses finite nonrenewable resources and may impact the health of the public.

We encourage physicians to think about the important role they have in public health policies and initiatives. Whether or not they are formally trained in the public health field, all physicians are protectors of the health of the public.

In this role physicians must act as advocates for patients who are abused and work to improve health literacy. They must maintain high standards of patient care and

also think about cost-effective medical practice. Physicians must educate patients about lifestyle choices and other preventive medicine measures before their health deteriorates, which means discussing a reasonable postpartum weight-loss program with a patient who is in her third trimester of pregnancy; talking to a recently divorced, middle-aged patient about healthy stress relief and a low-salt diet before his blood pressure skyrockets. It means recounting the dangers of smoking and the monetary savings of quitting to smoker-patients rather than just checking the box marked, "Smoker, Yes" and insisting that elderly patients get flu vaccines.

It means standing on your soapbox of healthy living with all your patients and recognizing that decisions physicians and patients make during individual clinical encounters add up to public health decisions.

Susanna Smith is a research associate in the AMA Ethics Standards Group.

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CASE AND COMMENTARY
Asking Patients about Intimate Partner Abuse, Commentary 1
Commentary by Michael A. Rodriguez, MD, MPH

Case
This was the second time Dr. Mike Ricardo had seen Mrs. Ashley Wills for a possible broken bone. A few months ago Mrs. Wills came in saying she had slipped that morning when she went out to get the mail. She had bruising on her arms and neck, and her left wrist was broken. When Dr. Ricardo asked Mrs. Wills how she had gotten the bruises on her neck from falling in the driveway, Mrs. Wills had looked down at the floor and shaken her head without responding. Dr. Ricardo found it difficult to believe that Mrs. Wills' husband, a well-respected attorney in town, would be physically violent to his wife, but that is where the signs were pointing. Now Mrs. Wills was back complaining that her ribs hurt when she breathed. One of the nurses stopped Dr. Ricardo in the staff room as he headed over to the exam room where Mrs. Wills' was waiting,

"Hey Mike, I was just in 3 with Ashley Wills. She's saying her ribs hurt when she breathes, and it looks like one might be fractured. She's got mean bruises on her cheek and her arm. She said that she fell when she was out jogging, but I don't believe her for a second. Can't you get her to report it?"

Commentary 1
Intimate partner abuse (IPA) is a major social and health problem that impacts more than one-third of American women at some point in their lives.[1] Half of all female survivors of IPA report injuries, and 20 percent of them seek assistance from clinicians.[2] The immediate health consequences of IPA can be severe and sometimes fatal, and women with a history of abuse have greater chronic and behavioral health risks.[3, 4] On average, more than 3 women are murdered by their husbands or boyfriends in this country every day.[2]

While clinicians routinely screen women for other potentially deadly but preventable conditions and behaviors such as high blood pressure and cigarette smoking, only 10 percent of primary care physicians ask their patients about abuse,[5] which may be more likely to affect their health and endanger their lives.

Many survivors of abuse have realistic fears that disclosing the abuse will jeopardize their safety by potentially escalating violence, exposing them to embarrassment, and jeopardizing their family, as well as putting them or their loved ones at risk for other hardships.[6] Quite often survivors whose primary language is

not English have difficulty relating their situation to hospital staff. Limited utilization of professional translator services causes reporting to rely on translation by family members, children, and partners, making some patients more reluctant to disclose information.

Clinicians may not screen patients for abuse because of their own discomfort and embarrassment, lack of time, fear of offending the patient, lack of training in knowing what to do when abuse is detected, or knowing what to do but believing it will not help.[5]

Despite these barriers, clinicians and health care facilities can implement a policy that can save lives and dollars. This policy simply relies on clinicians taking the time to ask their patients one critical question: *Do you feel safe at home?* Alternative screening questions can be found in the resources listed at the end of this commentary.

With regard to the case study, Dr. Ricardo has been confronted with a second opportunity to address a serious case of probable intimate partner abuse. It is apparent that Dr. Ricardo was reluctant to confirm his suspicions about abuse when Mrs. Wills first presented with injuries. Dr. Ricardo should have put his preconceived judgments aside and asked Mrs. Wills about abuse in a direct and nonjudgmental way. A majority of women patients favor physician inquiry and report that they would reveal abuse histories if asked directly.[7] Dr. Ricardo may have been able to prevent Mrs. Wills' second visit to the hospital had he taken appropriate measures the first time. Some of the actions he can take include but are not limited to:

- Ensuring the safety of his patient and any children;
- Respecting her life choices;
- Holding the perpetrator responsible for the abuse;
- Providing phone numbers of hot lines, health care, legal and other resources;
- Scheduling follow-up appointments;
- Encouraging a safety plan for the future.

In addition to clinicians' individual actions, there are several other ways of creating a supportive environment such as: (1) hanging posters about preventing IPA in waiting areas and patient rooms, (2) placing victim safety cards in the bathroom and exam rooms for patients who need information but may not be ready to disclose, and (3) wearing "Is someone hurting you? You can talk to me about it" buttons.

As part of a strategy to have more clinicians respond to IPA, at least 6 states have passed mandatory reporting laws for injuries resulting from IPA. These laws have stirred much ethical debate in the medical literature. Concerns are that mandatory reporting may increase violence by the perpetrators, diminish patients' autonomy, and compromise patient-physician confidentiality. Supporters of the policy argue that it will facilitate the prosecution of batterers and encourage clinicians to identify

intimate partner abuse. Because of the uncertain benefits of these mandatory reporting laws, the National Research Council has recommended a moratorium on such laws until more research is conducted on the advantages and disadvantages of mandatory reporting policies for partner abuse.[8]

Whether or not clinicians report intimate partner abuse, they should confront the issue, so survivors can seek support and counseling as well as information about shelters and other resources. We have the opportunity to help the many hidden survivors of IPA in our community, but only if we properly screen patients, identify abuse, and provide referrals.

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CASE AND COMMENTARY
Asking Patients about Intimate Partner Abuse, Commentary 2
Commentary by Tracy Battaglia, MD, MPH

Case
This was the second time Dr. Mike Ricardo had seen Mrs. Ashley Wills for a possible broken bone. A few months ago Mrs. Wills came in saying she had slipped that morning when she went out to get the mail. She had bruising on her arms and neck, and her left wrist was broken. When Dr. Ricardo asked Mrs. Wills how she had gotten the bruises on her neck from falling in the driveway, Mrs. Wills had looked down at the floor and shaken her head without responding. Dr. Ricardo found it difficult to believe that Mrs. Wills' husband, a well-respected attorney in town, would be physically violent to his wife, but that is where the signs were pointing. Now Mrs. Wills was back complaining that her ribs hurt when she breathed. One of the nurses stopped Dr. Ricardo in the staff room as he headed over to the exam room where Mrs. Wills' was waiting,

"Hey Mike, I was just in 3 with Ashley Wills. She's saying her ribs hurt when she breathes, and it looks like one might be fractured. She's got mean bruises on her cheek and her arm. She said that she fell when she was out jogging, but I don't believe her for a second. Can't you get her to report it?"

Commentary 2
Intimate partner violence (IPV) has become a widely recognized public health concern in the past few decades as a result of ongoing research that indicates a high prevalence of IPV with severe health consequences. Competence by health care professionals in screening for violence in intimate relationships has increasingly become a standard of care. The case of Dr. Mike Ricardo and Mrs. Ashley Wills highlights the fact that practicing clinicians continue to have difficulty integrating this standard into their everyday practice, and many IPV survivors do not readily disclose abuse, even when asked.[1, 2]

Violence against women is widespread in the United States. The National Violence Against Women Survey found that over 50 percent of women reported a lifetime history of physical assault, while for 25 percent of women that violence was perpetrated by an intimate partner.[3] IPV, also known as domestic violence, includes physical, sexual, and psychological assault. Psychological and emotional abuse are the most prevalent; as many as 75 percent of all women will be subjected to psychological aggression by an intimate partner in their lifetime. Studies have also found that women in abusive relationships have higher utilization of health care

services and will often access the health care system multiple times prior to abuse detection. Consequently, health care professionals are in a unique position to regularly encounter women who are survivors of violence.[4]

The first step in clinical practice is to identify the presence of violence. Ideally, this should occur during routine screening, prior to an acute injury. In fact, identifying violence through disclosure is therapeutic in itself, inasmuch as it validates the presence of an intensely private matter and is a requisite step in the healing process. Identification of IPV begins with direct physician inquiry. This case demonstrates that, despite standards setting, only about 10 percent of physicians screen patients routinely, while 80 percent inquire in the presence of suspicious injury. This is important since most women will not volunteer their histories and will avoid presenting with dramatic or suspicious injuries.[4]

Physicians cite lack of knowledge, skill, resources, and time as well as their beliefs or misconceptions and personal experiences as reasons for not screening their patients for IPV.[5, 6] Physicians fear that identification of IPV among their patients is like opening "Pandora's Box," which translates into time-consuming, complex care that requires expertise or resources they do not possess. Studies have shown, however, that survivors find it useful and empowering when health care professionals offer them education and referral to community resources. A statement such as "you don't deserve this" may go a long way for a woman who has never been told such abusive behavior is not acceptable. Even in the absence of on-site resources, physicians can easily provide statewide hotline numbers and program information.

Dr. Ricardo's disbelief that Mr. Wills, a well-respected attorney, could be a perpetrator of violence is a common misconception. Like Dr. Ricardo, many physicians falsely believe that violence only occurs among poor women of color. Although research has identified characteristics most often associated with a perpetrator of IPV, it is critical for physicians to be aware that any person regardless of gender, race, or socioeconomic status, can be a perpetrator of violence.[4] A high index of suspicion is necessary for all patients, since all women are at risk. Hence, the American Medical Association recommends direct questioning of all patients for IPV routinely.[7] Although we do not know the prior visit history in this case, it seems that Dr. Ricardo did not follow these guidelines.

Even in response to direct inquiry, patients may choose not to disclose. Physicians with expertise in IPV admit to difficulty identifying the presence of abuse in all cases.[5] Shame, guilt, and fear of perpetrator retaliation are some reasons women choose not to disclose when asked. Another barrier identified by both survivors and their physicians is lack of patient trust in the health care professional.[5, 8] Some or all of these factors may play a role in why Dr. Ricardo was unsuccessful in obtaining disclosure from Mrs. Wills.

One recent study of trust in the patient-physician relationship identified certain physician behaviors that facilitate trust and, thus, make disclosure more likely.[9] Many of these behaviors represent the essentials of a patient-centered approach in which the doctor and patient share power and responsibility through a therapeutic alliance. Survivors describe trusted physicians as those who engage in open communication where medical decision making is shared and allow them to maintain some control after suffering under the power and control of their perpetrator. An explicit explanation of the confidentiality of the patient-physician relationship directly facilitates trust, especially when the use of information has potential consequences for the patient, such as retribution from the abuser or involvement of child protective services. Survivors of IPV are more likely to trust physicians who are familiar with them through repeated encounters and who show concern through nonjudgmental and empowering statements or gestures. Similarly, physician persistence in repeated questioning while respecting the decision not to disclose conveys a sense of caring. And a physician who shares personal information facilitates trust by eliminating the inherent imbalance of knowledge and power in the patient-physician relationship.

As Dr. Ricardo prepares to enter the exam room with his patient, Mrs. Wills, he has a unique and powerful opportunity for intervention. His ongoing relationship with Mrs. Wills through repeated encounters already lends him credibility. The fact that Mrs. Wills chose to seek care in his office as opposed to in an emergency department provides some evidence of trust in her relationship with his office. If Dr. Ricardo can overcome his prior misconceptions and follow a patient-centered approach of direct questioning and explicit confidentiality, he may increase Mrs. Wills' trust and get closer to a disclosure of abuse. Even in the absence of a direct disclosure, Dr. Ricardo can provide education and referrals that Mrs. Wills may use in the future, or at the very least empower her to return once again to his office for further care and repeated questioning.

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CASE AND COMMENTARY
Please Don't Say Anything: Partner Notification and the Patient-Physician Relationship, Commentary 1

Commentary by Ronald Epstein, MD

Case

On Dr. Singh's recommendation, one of her patients, Mr. Henry Roland, consented to be tested for HIV and had a positive test result, which he feared but suspected. Mr. Roland has a longtime girlfriend, Lisa, whom he sometimes mentions to Dr. Singh. When talking to Mr. Roland about his positive test result, Dr. Singh brought up the topic of notifying Mr. Roland's past and present partners so they could be tested themselves. Mr. Roland refused to agree to tell Lisa, or even allow Dr. Singh to notify the health department so they could call her to suggest that she be tested.

"If she's positive, she'll know it was me. Please don't say anything or she'll know I gave it to her."

Mr. Roland told Dr. Singh that he intended to continue having sexual relations with Lisa, otherwise she would suspect that something was wrong with him. He insisted he would use protection consistently. Dr. Singh explained to Mr. Roland that Lisa may already be HIV-positive and if she is, she should seek treatment.

"She'll leave me if she knows. I can't deal with this without her, Dr. Singh, I just can't."

Commentary 1

While there might be general agreement that the ideal outcome of this difficult situation would involve disclosure to the partner as soon as possible, the pragmatics are not so obvious. The case description gives us little help, because the tools we need are embedded not in the facts of the case but in the patient-physician relationship.[1, 2] We know little about the prior relationship between Dr. Singh and Mr. Roland or between the physician and Lisa. We don't know much about the beliefs that may underlie each person's actions. But, for argument's sake, let's assume that there is a patient-physician relationship predating the HIV test, but, perhaps, they have not had any situations that tested the relationship (as is usually the case with otherwise young, and presumably healthy, men). Let's also assume that Mr. Roland is no longer an adolescent, has no other current sexual partners, and is not actively using intravenous drugs. And, for argument's sake, let's consider that Dr. Singh did a good job of pretest counseling. She informed Mr. Roland about the medical implications—that HIV is a treatable but very serious illness, and that

treatment is often delayed until the immune system shows signs of malfunction—and the psychosocial implications—that partner notification and family support would both be important.

Now that the patient has returned and received the test result, Dr. Singh tries to follow through by bringing up partner notification. If this is the same visit in which bad news has been delivered (no matter how gently and empathically), the patient is likely struggling to make sense of his own future, much less anyone else's.[3-6] When Dr. Singh brings up the issue of partner notification, Mr. Roland cannot face the stark choice that appears to have no viable answer: either betraying his lover or losing her.

Dr. Singh knows that scolding, threatening, and berating occasionally motivate humans to act responsibly, but these are not reliable tools.[7] Even if partner notification is mandated by law (as it is in New York State), the physician faces the dilemma of timing. Is this the time to persist? Would it be responsible to ask the patient to come back in a few days or in a week to discuss this further? After all, Mr. Roland could infect Lisa between now and then. Should Dr. Singh warn Lisa herself? Or how about contacting the public health authorities? They would likely send an officer to Lisa's home to advise her to be tested. The physician is in a dilemma similar to Mr. Roland's: she can insist and run the risk that the patient will never return or wait and run the risk that Lisa will become infected.

This may call for an imperfect temporary solution to preserve any possibility of long-term success. It may have to suffice to say, "I know that this has been too much bad news for one day. Maybe we should talk more next time. How about next week? But between now and then, please protect the one you love. And, is there someone with whom you can share this news who will help you through this week?" This way, Dr. Singh expresses empathy rather than disdain.[8, 9] She expresses concern for both the patient and his partner, and introduces the idea that the patient, similarly, might be able to find a way to care for himself and also Lisa at the same time. And, finally, Dr. Singh makes a suggestion for a short-term plan with an implied agenda. The patient is anxious, but knows that he will be understood.[10]

If we have gained the patient's trust, he returns. As often as not, he may have found a way to tell his partner. She may have threatened to leave him, but, as often as not, she may display unexpected support. But, what if she still does not know? To help Mr. Roland, Dr. Singh has to try harder and overcome any awkwardness she might feel.[11] She is careful not to coerce or threaten; she tries to understand the patient and to find some aspect of this patient with which she can work to create a stronger therapeutic bond.[12] Dr. Singh might ask, "What is the most frightening thing about telling her?" Normalizing, coupled with an offer to work together may be useful: "Anyone would find this an incredibly difficult situation, but I think that we can find a way to deal with it." Sometimes anticipating a different outcome can be

helpful, "I don't know Lisa that well, but a large percentage of partners end up being very supportive."

When trust is stronger, the patient can be helped to examine his values and the schism between values and actions. Using a conditional (if...then) or third person grammatical construction can distance the patient from the frightening immediacy of the situation while helping him to brainstorm: "What if you somehow found the courage to tell her. What might you say?" Or, "If it were a friend of yours who just tested positive, what would you say to him?" Offering options can motivate the patient to disclose: "You know that this has to happen, but the question is how. Would it be better for you to tell her or to have the health department tell her? There are advantages to both." Self-confidence and self-efficacy can be reinforced through gentle cajoling: "I know that you can." Role reversal can add another perspective: "What would you want her to do if she were you? Would you be able to still love her?"

These solutions are not perfect. Sometimes conflict is unavoidable. The ante may need to be raised. The physician might say, "I will not be able to live with myself unless I know that Lisa is adequately informed." Or, the law can be invoked, "State law requires me to make sure that Lisa knows. But, I would strongly prefer to do it in a way that we can both find acceptable." Rarely, the patient-physician relationship may be severed to protect a third party. The worst outcome, though, would be if the patient did not disclose, and did not return for follow-up. Desperation might lead him to jeopardize his own life as well as his partner's.

It is not known how often patients inform partners and what percentage of sexual partners have been informed. Even untreated patients with HIV may be asymptomatic for over 10 years, so sometimes there are many partners who should be informed. How hard should the patient and physician try? What about the 1-night encounter 14 years ago with someone who has since moved away? Some standard of reasonableness should be applied, but there are no rules to dictate those standards.

Partner notification requires knowledge of relevant options, laws and ethical standards, skills to communicate effectively, and the practical wisdom to know when and how to put that knowledge and those skills into action. Although it is often framed as a conflict, it can and should be done in a way that supports that part of the patient that wants to do the right thing. Most importantly, the physician should have sufficient self-awareness to recognize and adjust for prejudicial attitudes;[13, 14] we all have these biases; it is how we handle them that can build or destroy a relationship.

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CASE AND COMMENTARY
Please Don't Say Anything: Partner Notification and the Patient-Physician Relationship, Commentary 2

Commentary by James C. Thomas, MPH, PhD

Case

On Dr. Singh's recommendation, one of her patients, Mr. Henry Roland, consented to be tested for HIV and had a positive test result, which he feared but suspected. Mr. Roland has a longtime girlfriend, Lisa, whom he sometimes mentions to Dr. Singh. When talking to Mr. Roland about his positive test result, Dr. Singh brought up the topic of notifying Mr. Roland's past and present partners so they could be tested themselves. Mr. Roland refused to agree to tell Lisa, or even allow Dr. Singh to notify the health department so they could call her to suggest that she be tested.

"If she's positive, she'll know it was me. Please don't say anything or she'll know I gave it to her."

Mr. Roland told Dr. Singh that he intended to continue having sexual relations with Lisa, otherwise she would suspect that something was wrong with him. He insisted he would use protection consistently. Dr. Singh explained to Mr. Roland that Lisa may already be HIV-positive and if she is, she should seek treatment.

"She'll leave me if she knows. I can't deal with this without her, Dr. Singh, I just can't."

Commentary 2

There are at least 3 ethical threads running through this case: partner notification, disease reporting for surveillance purposes, and Mr. Roland's dishonesty and self-interest in his relationship with Lisa. Each of these highlights some aspect of public health ethics.

Whereas medical ethics is defined in large part by the interactions between a clinician and a patient, public health ethics is defined by the interactions between an agency, such as the health department, and a population of people. The agency is concerned about the well-being of the whole population, including the risk that one member can bring to the other members of the community. For this reason, public health ethics views the world through the lens of interdependence rather than the lens of autonomy.[1] We are interdependent in that one person's risk depends on another person's infection.

Mr. Roland illustrates for us how an infected person will not always act in the best interest of the uninfected person. He is willing to put his girlfriend's life at stake so he won't have to confront the reality of their relationship. (Deception is evidently part of their reality since he assumes he did not get his infection from Lisa, but from a person that Lisa doesn't know about.) Unfortunately, such self-interest and denial are common.

Out of an awareness that individuals with sexually transmitted diseases (STDs) are often hesitant to name their sexual partners and that clinicians may yield to the self-interest of the patient and also not report an infection to those who will notify sexual partners of their risk, state governments legally require that certain STDs be reported to the health department. Thus, when a clinician diagnoses syphilis, for example, reporting the infection to the health department is neither at the patient's nor the clinician's discretion. Once reported, a disease intervention specialist contacts the infected person and elicits the names and contact information of people with whom the infected person has had sex within the infectious period. Once found, the sexual partner is tested for infection and, if found to be infected, is treated. By shortening the duration of infection, the harm to the infected partner is minimized, as is the chance for transmission to still others.

The benefit of reporting HIV infection is not as clear cut as it is for syphilis. When syphilis is found, the infection can be cured. But that is not the case with HIV infection. In part because this benefit is not available for HIV, not all states require that HIV infections be reported. Current treatments reduce the viral load and thus decrease infectiousness, reduce perinatal transmission in pregnant women, and generally postpone AIDS and death. These benefits are enough that the Centers for Disease Control and Prevention (CDC) now recommend that all states require HIV reporting. CDC also argues that HIV reporting is necessary to monitor the epidemic and thus to better respond to it.[2]

We don't know where Dr. Singh practices, so we don't know if she is required to report Mr. Roland's infection under state law. If there is significant risk of transmission, it is unlikely that Dr. Singh would be legally liable if she were to report the infection when she is not legally required to do so. The ethical duty to protect others from an HIV-infected man who intends to have sex without telling his partner(s) of his infection would compel Dr. Singh to report the infection to the health department. Some argue that a reporting requirement causes fewer HIV-infected individuals to get tested because they fear what will happen if their infection becomes known. If many people do this, testing and reporting will have the unintended consequence of leading to *more* undiagnosed infections and thus more transmission. For this reason some states offer anonymous testing, in which the name or contact information of the person being tested is not known to the clinician. The situation we are dealing with in this case, however, is a known infection in a known person.

It *is* clear that Mr. Roland would be legally liable if he were to have sex while knowingly infected with HIV and not informing his sexual partner, as he intends to do with Lisa. This is often treated as a felony offense which can result in a prison sentence. Moreover, a strict reading of the law does not allow use of a condom as an excuse for not informing.[3]

Viewed from a public health perspective, Mr. Roland has an ethical duty to inform Lisa and his other sexual partners of his infection. He can do this himself or he can let the health department do it for him. If he has sex again he also has a legal requirement to inform his partners. Dr. Singh has the ethical duty, and likely the legal mandate, to report Mr. Roland's infection to the health department. The importance given by public health to the protection of the community leads to this course of action.

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CASE AND COMMENTARY
Please Don't Say Anything: Partner Notification and the Patient-Physician Relationship, Commentary 3
Commentary by Gregory W. Rutecki, MD

Case
On Dr. Singh's recommendation, one of her patients, Mr. Henry Roland, consented to be tested for HIV and had a positive test result, which he feared but suspected. Mr. Roland has a longtime girlfriend, Lisa, whom he sometimes mentions to Dr. Singh. When talking to Mr. Roland about his positive test result, Dr. Singh brought up the topic of notifying Mr. Roland's past and present partners so they could be tested themselves. Mr. Roland refused to agree to tell Lisa, or even allow Dr. Singh to notify the health department so they could call her to suggest that she be tested.

"If she's positive, she'll know it was me. Please don't say anything or she'll know I gave it to her."

Mr. Roland told Dr. Singh that he intended to continue having sexual relations with Lisa, otherwise she would suspect that something was wrong with him. He insisted he would use protection consistently. Dr. Singh explained to Mr. Roland that Lisa may already be HIV-positive and if she is, she should seek treatment.

"She'll leave me if she knows. I can't deal with this without her, Dr. Singh, I just can't."

Commentary 3
"Client-provider" confidentiality has been essential to the integrity of the learned professions for centuries, in fact dating back to a time long before the common era (BCE). Privileged communication is critical to the intimate conversations that characterize medicine, law, and religion. The earliest explicit codification of confidentiality in this context is contained in the Oath of Hippocrates (circa 400 BCE). "Whatsoever in the course of practice I see or hear, or even outside my practice in social intercourse, that ought never to be published abroad, I will not divulge, but consider such things to be holy secrets."[1] Other medical oaths, written throughout recorded history, are characterized by rich cultural diversity—emanating from Islamic, Hebrew, Hindu, and Daoist sources, for example—and agree substantively with the tenets of the Hippocratic Oath and Corpus, including agreement on the issue of confidentiality.

The confidentiality mandate has been so important that other professions have followed medicine's lead. The durability of confidentiality in patient-physician, advocate-client, and priest-penitent interactions speaks to an almost universal penetration through eastern and western culture.

Although the professional's obligation (confidentiality) to keep the secrets of the other party (their right to privacy) can be agreed upon as a common good, are there any limits? The answer to this question is the crux of any ethical discussion related to Dr. Singh and Mr. Henry Roland. Would Dr. Singh breach any of the accepted precepts of the patient-physician relationship if she contacts Lisa with the news of her intimate partner's HIV status? Let's try to answer that question.

Hipppocrates' Oath adumbrated the principle of professional privacy and influenced cultures separated widely by time and worldview perspective thinking. However, it seems that one statement in the Oath regarding privacy, namely, "Whatsoever (of what is seen or heard) … that ought never to be published abroad," implies that there are times or contents of intimate conversation that should, by their very nature, be "published abroad." If this remains true today, it suggests that a "relative" rather than absolute value be applied to the "good" of keeping confidences that arise during medical encounters. What would specifically qualify as more important than the protection of privileged information? How about the protection of life itself as a higher good? If keeping the secret endangers life, limited sharing, to those who have a valid "need to know," is an ethical imperative.

Earlier attempts to provide limits to privacy included the scholarly physician Moses Maimonides. In his Mishneh Torah, preserving life took precedence over many other "goods," even one as strict as Sabbath keeping. But for contemporary audiences, represented by many individuals who rely on legal precedent, the rationale justifying dissemination of privileged information has to be developed in more detail.

In 1969, Tatiana Tarasoff was stabbed to death by her boyfriend. Prior to her murder, the boyfriend confided to his therapist that he intended to kill Ms Tarasoff. The courts ruled that the therapist had a legal duty to warn Ms Tarasoff despite the fact the relevant information in question was considered protected by client-therapist privilege. As precedent, the judges quoted prior case law that determined that contagious diseases were to be reported if innocent parties outside the protected relationship were placed at risk.

More specifically, the courts have ruled similarly related to HIV positivity. Jennifer Lawson, a 12-year-old, was transfused with blood in 1985.[2] One day later, her physician discovered that the transfused blood was HIV-positive. The physician did not tell Jennifer or her parents about the tainted transfusion. Three years later, Jennifer became intimate with Daniel Reisner. Two more years later, Jennifer developed AIDS and told Daniel. One month after that, Jennifer died of her disease. Daniel sued Jennifer's physician. The judges ruled in favor of Daniel and against

the physician in question. The court's opinion was recorded thusly, "When the avoidance of foreseeable harm to a third person requires a defendant to control the conduct of a person with whom the defendant has a special relationship (such as physician and patient) or to warn the person of the risks involved in certain conduct, the defendant's duty extends to a third person with whom the defendant does not have a special relationship." *People v Jensen*[3] likewise decided that "HIV carriers must notify sexual partners." The duty to warn has been similarly applied in *DiMarco v Lynch Homes-Chester County*[4] concerning the sexual transmission of hepatitis-B virus to a third party.

From a strictly legal perspective, Dr. Singh is obligated to notify Mr. Roland's sexual contacts. Therefore, the Hippocratic Oath, other medical oaths from a diverse cultural sampling, Moses, Maimonides, and the courts as far back as the "Typhoid Mary" era have understood professional confidentiality as a good but a relative good. The preservation of human life is a far greater good, even if the life in question is outside the immediate context of a specific patient-physician relationship.

From a professional and logistic perspective, Dr. Singh could soften the blow a number of ways. She should encourage Mr. Roland to tell his partner because it is the loving thing to do, she has a right to know, and harm could ensue if she isn't informed. She could apprise Mr. Roland of the legal implications, for both the physician and patient, if sexual partners are not notified. She can reassure her patient that the confidence will only be shared with those who need to know, excluding all others. She could also educate Mr. Roland that "safe sex" with a condom is not a fail-safe guarantee that he will not transmit the virus to his partner. Some of the emotional stress of these particular encounters could be obviated in the future if physicians would inform their patients about the relativity of privileged sharing prior to intimate conversations. In fact, sharing diversity and worldview perspectives before contentious issues arise is good for the patient-physician relationship. To many patients, the physician's primary commitment to the protection of life should be viewed as a wonderful attribute.

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CASE AND COMMENTARY

"Concierge" Practice and the Profession's Contract with Society

Commentary by Troy Brennan, MD, JD, MPH

Case

Dr. Leanne Todd, a primary care physician in a small town, has become tired of constantly apologizing to her patients for the hours they spend in her waiting room, her overbooked appointment book, and the constant rush of having to move on to the next patient. The 15-minute time slots Dr. Todd's scheduler allots do not permit her to have a personal conversation with each patient or allow them to air all of their health concerns.

After some serious thinking and conversations with a colleague and an old friend of hers in Florida, Dr. Todd has decided that she will transform her current practice into a concierge medicine business. She has worked out the finances and realized that she doesn't have take a pay cut if she has fewer patients and charges them more, and it will be more satisfying for the patients, more fulfilling for her, and less stressful for her staff.

Dr. Todd has sent each of her current patients a letter explaining that she will be changing her practice and that they will be charged a flat annual fee of about $3000 to continue to see her. The letter explains that under the new practice set-up Dr. Todd will have fewer patients and will offer same-day appointments with more time to talk to the doctor. Dr. Todd will also start making house calls and carry a cellphone so her patients can reach her 24 hours a day. She tells her patients that she will continue to keep appointments as scheduled for the next 6 months but will not schedule any new nonurgent visits for patients who do not wish to participate in the new practice. Each letter contains a list of other physicians in nearby towns complete with the type of insurance each physician accepts for patients who do not wish to join Dr. Todd's concierge plan and decide to change doctors.

Since the letter was sent out, Dr. Todd's office has been flooded with phone calls from her patients. Some of her patients are willing to pay the extra fee and are thrilled with the opportunity to receive more personal attention. Although Dr. Todd's staff is overwhelmed with all the phone calls, they are looking forward to the practice transition and the chance to work with fewer patients. Mrs. Liles, a 73-year-old patient, has called 4 times since she received her letter. She insists to the staff that an exception be made for her and that Dr. Todd continue to see her.

Mrs. Liles lives down the street from Dr. Todd's office and does not drive. The closest primary care physician is a 30-minute drive away. Mrs. Liles keeps telling the staff that they must inform Dr. Todd that she doesn't drive and that she should be allowed to continue to see Dr. Todd without paying the extra fee.

Commentary 1

The evening I received the invitation to read and comment on this case study, I was late to rounds on a patient who had just undergone cardiac catheterization. She is a 63-year-old woman, somewhat disabled by diabetes and high blood pressure, who is insured by the Medicaid program. She had had some angina-type symptoms and failed a stress test, leading to the catheterization study. The angiograms showed only single vessel disease that was not amenable to stenting, and the cardiology team recommended medical management.

When I entered the room, she was surrounded by 2 friends, a case manager, and her nurse. It was 7PM, but she was getting ready for discharge since the hospital was very crowded and her catheterization had gone smoothly. When she saw me, she nearly shouted, "Dr. Brennan, I am so mad at you! Where have you been?" It was true I had not been in to see her the night before (she was a rare admit-the-night-before case because of her often brittle diabetes), and she had found herself beset by fellows and attending physicians from the cardiology service who had "told me about a million things that could go wrong and confused me terribly!" She said all of this with a big smile on her face, especially when I assured her that the doctors had been in touch with me throughout the stay, and that we were all pleased with her progress. We had a very nice visit and developed a clear game plan for the next few days so that we could keep an eye on her renal function and diabetic control postcatheterization. Her trust in me was very gratifying, but I did feel bad about not guiding the process the night before. I had let her down.

We are old friends, in the special, formal kind of way that a doctor becomes friends with old patients. We talk when she sees me in clinic about a variety of her personal matters, and she likes to hear about my family and life. I very much enjoy her company, knowing that it is not a relationship of friends, but a professional one. She depends on me to ensure her health stays passably good, and I have responsibilities to her that neither she nor I expect her to reciprocate. I have known her for a long time, and know her diseases pretty well, and we have been successful in keeping her relatively healthy. She interrupts my personal life with calls when things are going poorly, and on more than one occasion I have had to depart from social events or family time to see her in the hospital. All this is no big deal, it is the way that most primary care doctors take care of their patients.

Now how could I possibly tell her, "Guess what, you now have to pay me $3000 per year to take care of you"? She could not afford it and would have to find a new doctor and in many ways start over in building relationship. I would lose a friend, but moreover, I think I would corrode in my own mind the sense of a special relationship with my patients. I do get paid for caring for them, but I care for them

because I enjoy being a doctor. Telling this patient and others like her that I cannot continue my relationship with them when I enter a concierge practice would change all of that. And my patient, I can imagine, just barely, how perplexed and hurt she would be.

Forget about all the policy and ethics and economics arguments that can be made against concierge medicine, and just focus on this: what is the meaning of a patient-physician relationship if it can be terminated abruptly and for such coarse reasons? I hope that reflecting on that point will lead most physicians to reject the concept so that boutique practice will not become prevalent. If that is not the case, and we physicians cannot support all patients in the way our professional values guide us, then we risk losing our special voice in matters surrounding the organization of health care.

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IN THE LITERATURE
Physicians' Role in Cost Containment
Renee Witlen

Ubel, P, Arnold R. The unbearable rightness of bedside rationing: physician duties in a climate of cost containment. *Arch Intern Med*. 1995;155:1837-1842.

In their 1995 article, "The Unbearable Rightness of Bedside Rationing: Physician Duties in a Climate of Cost Containment," Drs Peter Ubel and Robert Arnold assert that physicians should engage in bedside rationing in order to contain rising health care costs. They define bedside rationing as "physicians' actions to withhold beneficial care from patients that physicians were free to offer them" and confine their discussion to rationing done "either without patients being aware of the rationing or, less often, with patients being aware but being given no choice."[1] Many physicians and ethicists have rejected this role for physicians in the belief that physicians must advocate for the individual patient, even acting, if necessary, against the "apparent interests of society as a whole."[2] Ubel and Arnold contend that if bedside rationing is conducted correctly, it is morally acceptable and, in conjunction with rationing decisions at higher levels of health care organizations, constitutes the only viable way to contain health care costs in the short and medium term.

Ubel and Arnold are careful to specify how bedside rationing must occur in order for it to be morally acceptable. Decisions should be based solely on medical costs and benefits; physicians should not make resource allocation decisions on the basis of discriminatory criteria such as race or gender.[3] Furthermore, only "marginally beneficial" services should be rationed. Ubel and Arnold note that it is difficult to characterize the nature of "marginally beneficial" services. In order to determine which services can be considered "marginally beneficial," they encourage physicians to compare the cost-effectiveness of any particular treatment or diagnostic test to the cost-effectiveness of comparable alternative interventions. They urge physicians to apply cost-effectiveness considerations with caution, given that society is often willing to spend large sums of money treating patients with extreme needs, despite the low technical cost-effectiveness of some expensive, life-saving treatments. Ubel and Arnold also note that the implementation of bedside rationing should involve physician training on the cost-effectiveness of treatments, so that physicians are not left to engage in cost-effectiveness analysis at the bedside.[4] Physicians who are educated to identify marginally beneficial services will be able to make informed and ethical decisions about how best to treat their patients. For example, a physician educated about the cost-effectiveness of 2

diagnostic tests could make an informed decision to order a test with 90 percent sensitivity instead of a much more expensive one with 91 percent sensitivity.[5]

For Ubel and Arnold, relaxing the traditional "physician-as-patient-advocate" role is acceptable because other methods of cost containment entail more significant threats to the quality of patient care.[6]

"Without bedside rationing," they state, "we can only contain costs with a complex set of rules circumscribing physicians' actions, rules that are likely to harm patients whose specific medical conditions are not adequately captured by the rules."[6]

If physicians accept a bedside-rationing role, they may be able to contain costs while treating patients according to less complex and limiting rules. After considering the risks to patients posed by restrictive rules developed by health care organizations, Ubel and Arnold find that less restrictive rules (accompanied by the practice of bedside rationing) have the best chance to contain costs while optimizing patient health outcomes. Hence, the comparative benefits of bedside rationing render the practice morally acceptable.

Opposition to Bedside Rationing

Some ethicists have stated that physicians' attempts to advocate simultaneously for individual patient's best interests and for society's financial interests will disrupt the essential trust between patient and physician.[2, 7] Ubel and Arnold question this premise, stating that there is little evidence that bedside rationing damages the patient-physician relationship.

Opponents of bedside rationing have also objected to the practice on the basis that it may involve arbitrary and discriminatory treatment decisions. In his article, "Physicians, Cost Control, and Ethics," Daniel P. Sulmasy suggests that 2 patients with the same condition might be offered substantively different care options if their 2 doctors made different bedside rationing decisions. Sulmasy believes that such differences would constitute a serious injustice, and he describes bedside rationing decisions as "arbitrary and inherently inequitable."[8] Sulmasy believes that this problem could only be addressed by setting allocation rules at higher levels within health care organizations, so that each doctor, following treatment rules, would treat similar patients with a previously established set of services.[8]

This solution is vulnerable to the criticism, noted earlier, that predetermined treatment protocols might not accurately capture the nuances of clinical medicine, harming patients whose conditions are not well-described by such protocols. Ubel and Arnold also counter suggestions that bedside rationing could be discriminatory by noting that any form of resource allocation has the potential for discrimination; they observe, for example, that rationing care according to ability to pay discriminates against people with less money.[5] The authors suggest that careful oversight could protect patients from discriminatory decisions rendered during bedside rationing.

Marcia Angell raises a final important objection to bedside rationing in her article, "The Doctor as Double Agent."[9] Angell asserts that "enlisting doctors as ad hoc rationers presumes that resources saved by denying health care would be put to better use."[10] Since the United States does not have a "closed system in which funds taken from one form of health care are diverted to another that is deemed to be more important," funds diverted from any particular use could be reallocated to any other sector of the economy.[10] There is no guarantee that resources saved would be used to pay for a more cost-effective health care intervention. Ubel and Arnold respond to this critique by noting that "there is no morally compelling reason to argue that money saved on one health care service must go toward other health care services."[11] As other social goals equal in importance to health care provision do not currently receive sufficient funding, the authors believe it is both necessary and ethically permissible for physicians to engage in bedside rationing, even if resources saved might not be applied directly toward health needs.

Ubel and Arnold acknowledge that there are moral risks involved with bedside rationing, but they believe that potential problems with the practice have been overstated.[11] They state that failure to control the costs of health care is itself a moral problem which physicians have an important role in addressing. Ubel and Arnold believe that doctors should contribute to the solution of this problem by accepting and openly discussing the practice of bedside rationing, so that they can learn how to balance their roles as patient advocates and stewards of societal resources.

Questions for Discussion

1. Do you think that bedside rationing threatens the relationship of trust between doctors and patients?
2. Given that scarce health care resources must be distributed, do you think that doctors are in the best position to make decisions about their allocation? If not, what individuals or organizations are better suited to make these decisions?
3. Is it necessary for physicians to inform their patients of the range of available clinical services for their conditions? Alternatively, is it acceptable for physicians to order tests or treatments based on bedside rationing decisions without describing options a patient might pursue with her own funds had she been informed about them?

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Renee Witlen is a contributor to *Virtual Mentor.*

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HEALTH LAW

Grimes v. Kennedy Krieger Institute: Nontherapeutic Research with Children

Richard Morse, MA

In 1993, the Kennedy Krieger Institute (KKI) initiated research to study the effects of different lead paint abatement interventions on urban homes in the Baltimore area. The study stemmed from the government's desire to find a less costly means of lead paint abatement because the expense of full abatement was too high compared to the worth of the properties. Faced with the mandatory expense of full lead paint abatement, many landlords were abandoning the unprofitable houses in low income areas In an effort to forestall the seemingly inevitable abandonment of properties, the local government recruited and reimbursed the landlords for varying levels of lead paint abatement.

Group I homes received minimal repair and maintenance. Group II homes received a greater level of repair and maintenance than Group I homes. Group III interventions were more aggressive than both Groups I and II. Group IV homes were previously completely abated of lead paint, and no additional repairs were made. Group V homes received no repairs inasmuch as they were built after 1980 and presumed to be free of lead paint.

KKI recruited families with small children already living in these homes to take part in the study. The families were paid for allowing KKI to take periodic dust, soil, water, and blood samples. The effectiveness of the various abatement procedures was assessed "by measuring the extent to which the . . . healthy children's blood became contaminated with lead, and comparing that contamination with levels of lead dust in the houses over the same periods of time."[1]

Two children who were involved in the KKI study later sued. Ericka Grimes resided in one of the study homes from her birth in 1992 until her family moved in 1994. Grimes's blood lead level steadily increased throughout the experiment. She contended that KKI was aware of the lead paint hazards in the home. Grimes alleged that KKI breached its duty to the research subjects by not fully explaining the dangers of lead paint to children in the consent form that the families signed to participate in the study. Grimes also claimed that KKI "failed to warn in a timely manner or otherwise act to prevent the children's exposure to the known presence of lead."[2]

Myron Higgins began living in a partially lead abated home in May 1994. Higgins argued that KKI was also aware of the dangerous increase in the level of lead in his

blood from periodic blood samples, and failed to inform his mother of these unsafe and escalating levels. As with Grimes, the consent form signed by Higgins' mother did not contain a clear disclosure by KKI that the children might accumulate potentially dangerous levels of lead in their blood as a result of the experiment, and that the effects of elevated blood lead range from damage to the central nervous system and kidneys, to irreversible behavioral problems, to death.[3] Both Grimes and Higgins lawsuits based negligence claims on the theory that KKI performed the study in a manner that increased, rather than decreased, the children's exposure to lead.

KKI moved for summary judgment on the grounds that it did not owe a duty to the appellants and that no contract or "special relationship" existed between the researchers and the study subjects. The circuit court granted KKI's motion. The Court of Appeals of Maryland held that the circuit court erred in granting the motion because the determination of whether a "special relationship" existed between KKI and Grimes or Higgins involved a genuine issue of material fact. The rulings for both appellants were vacated (annulled), and both cases were remanded for new proceedings.

Legal Analysis

The Court of Appeals began its analysis with a review of the KKI consent form that both appellants signed. The court determined from an examination of the record that all necessary components needed to create a valid contract were present. Further, by having appellants sign the consent form, "KKI and the appellants expressly made representations, which, in [the court's] view, created a bilateral contract between the parties."[2] In this nontherapeutic study, the court concluded that the consent form created a contract.

Next, the court noted that no case law existed as to whether a "special relationship" exists between a researcher and a study subject when the nature of the study is health-related. It found the researcher-subject relationship differs from the patient-physician relationship on several counts. The research subject and the researcher may have conflicting interests, and nontherapeutic studies may involve unforeseeable risks. Considering this information and the consent forms that the subjects' parents had signed, the court held that a special relationship *did* exist between the researcher and the subjects.

The court distinguished the fact that the parents, not the study's subjects, signed the consent forms in this study. In the instance of "true" informed consent, the subject weighs the risks against the benefits and demonstrates a true understanding when deciding whether to consent. Implicit in informed consent is the subject's access to "all material information."[2] Despite this distinction, the court found that a contract existed between the researcher and the subjects.

The court further found that the special relationships that evolve from certain interactions between researcher and subject gave rise to duties that, if breached,

may result in a cause of action for negligence. Where the risk involves personal injury, privity of contract need not be shown and "the principal determinant of duty becomes foreseeability."[4] Here, lead contamination was foreseeable and even contemplated, since the level of lead in the children's blood would aid the researchers in measuring the effectiveness of the different abatement interventions. Therefore, the court found that an express contract was not necessary to maintain an action for negligence.

The court found that governmental regulations could create yet another way that a special relationship is established between researchers and study subjects. In the absence of a Maryland code, federal regulations provide standards of care for human research subjects. Where funding is provided by a federal agency, the *Code of Federal Regulations* (CFR) requires that any study using human subjects comply fully with informed consent requirements. Specifically, any new significant data that evolves as the study matures that may affect "the subject's willingness to continue" should be shared with the subject (45 CFR S 46 116).

The court noted that there was "more than minimal risk involved" in the KKI study and that increasing blood lead levels were detected in some research subjects. Further, under federal regulations and established ethical medical standards, children should not have been used to measure the effectiveness of partial lead abatement interventions.

Finally, the court held that parents cannot consent to exposing their children to a health risk that has no therapeutic value or benefit to the child even if for the "greater good" of society.[5] The court relied upon its long-standing policy of considering the "best interest of the child" in reviewing KKI's claim that it obtained adequate informed consent from the children's parents before issuing the study. The court insisted that a parent "may not consent to have a child submit to painful or potentially life-threatening research procedures that hold no prospect of benefit to the child."[6] The court put the burden on the researchers, assigning them primary responsibility for protecting children from harm in nontherapeutic research studies.

The court noted that the parents should have been told that it was likely that their children would ingest lead dust particles and that lead dust contamination would be measured in the children's blood to determine the success of the study. Additionally, the parents should have been informed that there was a chance that lead would actually accumulate in the children's blood. Because the consent form did not clearly make the parents aware of the potential harm to their children, the court deemed the agreement invalid and reversed the finding of the lower court.

Grimes v Kennedy Krieger Institute illustrates that society's interest in new and perhaps beneficial research may at times be in conflict with the interests of the individuals who are participating as research subjects. When the individuals participating in the study are children the issue becomes even more complex. In this case, the court struck a balance between this ethical conflict by creating Maryland

law that aggressively protects innocent children from potential harm and, in doing this, ultimately protects the health and welfare of society. In delineating 3 alternative ways a "special relationship" between researcher and human subject can be created, the Court of Appeals provided a flexible framework in which an injured research subject may seek redress. The court has emphatically stated that a vulnerable child will not be used to test potentially hazardous theories better left to a subject who is a well-informed, independent adult.

Discussion Questions

1. Opponents of the court's decision contend that it impedes the progress of public health research. In fact, they have argued that by not allowing children to participate in nontherapeutic research, the hands of the research community are tied, and ultimately children in the future will be the losers. Do you agree? If so, how should researchers get data that relates to children?
2. Research that involves greater than minimal risk without the prospect of benefit, such as nontherapeutic research, can only be permitted if the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. While the IRB approved this research project, what kinds of additional safeguards might they have instituted to protect the health of the research participants?

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STATE OF THE ART AND SCIENCE
Flu Vaccine Recommendations and Dosages
Audiey Kao, MD, PhD

About 10 to 20 percent of US residents contract the influenza virus each year, resulting in an average of 114,000 hospitalizations and 36,000 deaths annually.[1] The influenza virus causes flu, a serious respiratory disease that may present with symptoms similar to those of the common cold but is caused by a different virus. Common flu symptoms are:

- Fever,
- Headaches,
- Tiredness,
- Dry cough,
- Sore throat,
- Nasal congestion and body aches.

The flu is most common during the winter months; for North America the flu season is from November to March. Although anyone may get the flu, some people are more vulnerable to serious complications from contracting the virus. It is recommended that people at high risk for flu-related complications get an influenza vaccine each year in October or November.[2]

Flu shots are recommended for all patients who:[3]

- Are 50 years old or older;
- Are 6 months to 49 years old with 1 or more of the following conditions:
    - a chronic pulmonary or cardiovascular disorder including asthma,
    - a chronic blood, kidney, or immune system disease including HIV,
    - diabetes that has required medical follow-up or hospitalization in the past year,
    - a 2nd or 3rd trimester of pregnancy during flu season,
    - a child or teenager on long-term aspirin therapy.
- Reside in nursing homes or other chronic care facilities;
- Are likely to transmit the virus to a person at high risk such as:
    - health care workers, caregivers, or household members with a high-risk condition,
    - children 0-23 months of age or caretakers of children of this age;
- Are 6-23 months of age;
- Any other person older than 6 months who wishes to reduce the likelihood of getting the flu and does not have any contraindications.

Patients should not get the flu vaccine if they have had serious reactions (eg, anaphyalxis) to eggs or to a previous influenza vaccine or to one of its components. Healthy, nonpregnant people who are between 5 and 49 years old may receive the live attenuate influenza vaccine (LAIV). Persons with chronic diseases (eg, asthma, heart and renal disease, diabetes) that may put them at high risk when exposed to the wild virus should not be offered LAIV. People who are in close contact with immunosuppressed people should be given the inactivated influenza virus (IIV).

Vaccine Dosing and Administration[3]

- IIV may be given to patients older than 6 months. Patients between 6-35 months of age should be given 0.25 mL; patients 3 years old or older should be given 0.5 mL. Give IM with a 22-25g, *1*" needle.
- Healthy people between 5 and 49 years old may receive 0.5mL LAIV (0.25 mL in each nostril).
- Children who are younger than 9 years old and receiving a flu shot for the first time should receive 2 doses. For IIV, the doses should be separated by at least 4 weeks. For LAIV given to children 5-8 years old, the doses should be separated by at least 6 weeks.

Side Effects[3]

- Soreness and redness at the injection site lasting 1-2 days are the most common side effects of IIV.
- Runny nose and nasal congestion are the most common side effects of LAIV.

The vaccine is not always a perfect match for the virus circulating that season, but those who are vaccinated and contract the virus will likely experience milder symptoms. Physicians should remind patients that the best way to protect themselves and their loved ones from the flu is by getting vaccinated.

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STATE OF THE ART AND SCIENCE

The Genomic Era: What MUST Public Health Do?

Shane K. Green, PhD

In a recent paper proposing "a vision for the future of genomics," representatives of the US National Human Genome Research Institute (NHGRI) suggested that, "with the completion of a high-quality, comprehensive sequence of the human genome…the genomic era is now a reality."[1] The underlying assumption, that in this new era medical innovations born of genomics will lead to significant improvements in human health, is a safe one. Though unlikely to give rise to a panacea for genetically transmitted disease and dysfunction, our ever clearer understanding of the genetic underpinnings of disease will most certainly have a substantial impact on health care. As the NHGRI group went on to concede, however, the widespread application of genomics to health is some years away.

Those years provide a narrow window of opportunity for the creation and execution of public health initiatives that address the challenges inherent in bringing genomics into the clinic. To a limited extent, genomics has already begun to enter the public health sphere, as evidenced by the screening of newborns for various genetic conditions (eg, cystic fibrosis), and the use of genetic testing to identify carriers of heritable mutations that confer significant predisposition to certain forms of cancer (eg, BRCA1-linked breast cancer). With tests now clinically available for more than 600 genetic diseases from albinism to Williams syndrome,[2] much broader applications of genomics to health care are clearly imminent. Indeed, the time has come to move from suggestions of what *should* be done for public health to incorporate genomics into its purview to discussions of what *must* be done.

The many practical and ethical challenges facing public health in this grand and necessary endeavor have been explored to considerable depth elsewhere.[3] This brief article will focus on 2 of these challenges, the resolution of which will be of particular importance in allowing public health to fulfill its overarching mandate to seek and implement means of providing for and ensuring the collective well-being of the public.

The first and perhaps most pressing challenge is to foster significant improvements in "genetic literacy," which "includes knowing about benefits, risks, and limitations of genetic screening and testing, as well as the implications of genetic information."[4] Owing in large part to the somewhat esoteric nature of the science of genetics, a substantial segment of the public could presently be considered genetics illiterates. True, there are few people in developed countries who are completely

unfamiliar with DNA *per se*. However, just as knowing one's ABCs does not allow one to understand a book, knowledge of the ACGTs of DNA does not equate to understanding its potential medical applications and implications. Moreover, "genetic illiteracy" is a hurdle not only for members of the lay public but also for physicians, many of whom received their medical training before the clinical use of genetics made such literacy necessary.

Genetic literacy for *all* is essential to secure maximal health benefits for the public in the application of genomics to health care. Physicians, ultimately responsible for the clinical use of genetic technology, must take the lead in ensuring that it is used to bring about actual improvements in the health of their patients. They must possess a sufficient level of understanding to appropriately advise their patients about the possible risks and benefits of increasingly numerous diagnostic and therapeutic options made possible through genomics. They must also knowledgeably field the inevitable questions from patients curious about genetic testing, or they will risk, among other things, losing patients' trust in their ability to provide competent care.

That said, patients with a basic understanding of genetics will be empowered to make informed decisions with respect to their care, where less-informed patients may forgo testing due to ignorance, misunderstanding, or fear. Hence, the best outcomes of genetic testing and treatment will likely result from patient-physician interactions in which the genetic literacy level is high for both parties.

Public health initiatives must therefore seek to raise genetic literacy if the promise of genomics is to be realized. This necessity has not gone unacknowledged; numerous groups, including the US Department of Health and Human Services, have deemed it a top priority. Prioritization, however, is a long way from accomplishment, with the 2 bridged by action. For example, state medical boards, some of which already mandate continuing medical education (CME) content, could raise the genetic literacy of practicing physicians by imposing minimum requirements for CME in genetics. Unfortunately, however, none presently do.[5] This or other broad-scoped policy-based approaches will be necessary to ensure that all physicians keep abreast of developments in health care genetics.

Effectively reaching the general public will prove more difficult. For example, since approximately 60 percent of Americans access the Internet, with 80 percent of them using it occasionally to search for health information,[6] patient-centered websites (eg, www.nationalhealthcouncil.org) could disseminate information on health care applications of genetics. Such an approach, however, would fail to reach the 40 percent of Americans who are not online. Similarly, coverage of health care genetics by television and print media reaches only those who choose such news items in favor of "The Simpsons" or the sports section. Therefore, innovative efforts must be undertaken to see that *all* members of the public are informed.

This raises what I see as the other great challenge to the successful integration of genomics into public health: ensuring public accessibility to benefits in the context of a health care system compromised by disparity. Unlike the patient-physician relationship, in which the obligations of the physician extend primarily to the individual patient, the raison d'être of public health is to seek and ensure the collective well-being of *all* members of the public. The single most important role for public health in ushering in the genomic era is to ensure that its benefits reach everyone.

With health care costs rising seemingly unabated, it is likely that medical applications of genomics, presently very expensive tools, will exacerbate the already troubling disparities in health care. Truly, the potential for a "genomic divide" exists not only between developed and developing nations,[7] but also between the socioeconomic strata within those nations. Thus, existing and foreseeable disparities must be assessed and must then be explicitly addressed by any policies instituted to govern the public health applications of genomics. Finally, the public must be unhesitatingly given demonstrable assurance that these considerations will be paramount and that genetic technologies will be made available to anyone for whom they hold the promise of improved health.

If the genomic era is to be one in which genomics, used wisely and effectively, achieves significant improvements in human health, public health must hold genetic literacy and avoidance of disparity as primary goals; without genetic literacy, implementation will be practically impossible; with disparity, implementation will be inadequate and unethical.

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POLICY FORUM
School Vaccination Laws
Erin Flanagan-Klygis, MD

Pediatric immunization programs have been one of the most important public health initiatives of the 20th century, with statewide immunization mandates for school and childcare entry playing a key role in their success in the United States. In the year 2000, the US had the highest immunization coverage and the lowest rates of vaccine-preventable disease ever documented.[1] In spite of this, the media, the Internet, and antivaccination groups continually stir up parents' fears with unscientific, sensationalized, and biased information linking vaccinations to everything from autism to diabetes. In fact, with disease burdens so low, media-reported rates of adverse events causally or temporally related to vaccination appear more common than the diseases themselves. As a result, vaccination laws have been questioned as an unnecessary affront to parental autonomy. Do vaccination laws have a place in a society that prioritizes personal freedom, especially when the risk of vaccine-preventable disease is so low? Could we see similar vaccination rates with a voluntary system?

History shows that state mandates play a key role in maximizing immunization rates, enabling protection of both individuals and the general population. Successful vaccination programs to some degree shift the policy balance away from personal autonomy and toward social responsibility. Specific exemptions from vaccine requirements ensure peaceful coexistence between the two.

Legally mandated vaccination emerged in the US in the late 19th century during a smallpox epidemic in Massachusetts. The Supreme Court upheld a Massachusetts law in 1905, ruling that state police powers include the right to protect the public against infectious disease by enacting universal vaccination requirements, paving the way for all states to adopt immunization legislation.[2] Laws requiring vaccination for school entry were upheld in 1922 by the Supreme Court. Modern childhood immunization initiatives began with efforts to eliminate indigenous transmission of measles in the US in the 1970s[3] Schools were major sites of disease transmission, and evidence showed that states with school immunization laws had rates of measles 40-51 percent lower than states without such laws.[4] As a result, school vaccination statutes were broadened in the late 1970s and more strictly enforced. Provision of free vaccines and threats of school exclusion without proof of vaccination proved highly successful in eradicating repeated, sustained measles outbreaks. Data from 6 states strictly enforcing comprehensive school laws were compared to data from states without enforcement.[5] In the first year, strictly

enforcing states had measles rates 50 percent lower than nonenforcers. By the second year, the measles rates in strictly enforcing states was 1/10 that of rates in other states.[6] Today, although states clearly have the power and authority to require universal vaccination during disease outbreaks, it is less clear how aggressively they should use that power when disease burdens and risks of infection are low.[6]

Parents may legally avoid vaccinating their children with personal exemptions. Three types of exemptions exist: medical, religious, and philosophical. All 50 states have adopted medical exemptions for children at significant risk from the vaccination, such as those with compromised immune systems. Religious exemptions exist in 48 states and permit individuals and parents to refuse vaccination on religious grounds. Philosophical exemptions exist in 19 states. These allow parents to refuse vaccinations without a specific religious justification. Of note, religious and philosophical exemptions account for only a small percentage of unvaccinated children. In 1998, the average percentage of children unvaccinated as a result of nonmedical personal exemption was 0.6 percent.[7]

When coverage rates for certain vaccines reach a high level, (between 85-95 percent depending on the vaccine), resistance to disease spread develops because a large portion of the community is immune, establishing "herd immunity," and allowing limited numbers of nonvaccinated individuals to enjoy relative protection from infection. So, what harm may result from a small measure of parental autonomy in the midst of low disease burden and high immunization coverage in the population? When parents exercise personal exemption and refuse vaccination for their children because of a perceived risk of adverse event or sequelae, they avoid risks of adverse events and take advantage of the partial protection created by herd immunity. If repeated by many, the refusals create vulnerable points of disease transmission and render the larger population more susceptible to contagious diseases that could cause significant morbidity and mortality. Feiken and colleagues studied records in Colorado over an 11-year period to determine whether individual and community risks of measles and pertussis disease increased as a result of religious and philosophical exemptions.[8] Their data showed Colorado to have the highest percentage of unvaccinated children due to personal exemption, 0.12 percent medical, 0.19 percent religious, and 1.87 percent philosophical. They found unvaccinated children 3-18 years old were 22 times more likely to acquire measles and 6 times more likely to acquire pertussis than immunized children. In children 3-10 years old, the risks were 60-fold greater for acquiring measles and 16-fold greater for pertussis. Rates of disease in vaccinated children exposed to exemptors increased as well. The annual rates of measles and pertussis among vaccinated children aged 3-18 years positively correlated with the frequency of exemptors, with relative risks of 1.6 and 1.9 respectively. This study confirmed that vaccine refusal poses risks to unvaccinated individuals and the health of the entire population.

No vaccine is 100 percent safe or effective. As vaccination rates go up, reports of vaccine-associated adverse events, both those caused by vaccines (ie, true adverse

reactions such as anaphylaxis) and those temporally associated with vaccination by coincidence, increase.[9] These reports adversely affect public perception (or misperception) of vaccine safety. Though millions of children have been vaccinated safely, the climate of public discourse about vaccine risk has changed, with fear of adverse events eclipsing fear of disease and many parents coming to view vaccination not as protective but as risky.

In general, we presume parents appropriately exercise surrogate decision making for their children and that they are in a better position than the state to promote the child's best interests.[6] The Supreme Court has upheld parental autonomy on several occasions,[10-12] although parental authority is by no means absolute. Parental autonomy may be limited by the state's interest in protecting children from harm and neglect. With respect to immunization, the growing fear of the risks of vaccines creates a serious public policy problem. Despite the lack of scientific data establishing a causal link between vaccines and chronic debilitating conditions, the flow of biased information from the Internet and the media has heightened parents' vaccine-safety concerns. If the risks of vaccination are misperceived to exceed the risks of the vaccine-preventable disease, then parents view vaccine laws as forcing them to put their children in harm's way.

A successful childhood vaccination program must respond to both sides of the social equation: parental autonomy and social responsibility. Laws that mandate vaccination for school entry provide the best protection against disease outbreaks for both individuals and the general population. Exemptions offer those with deep personal beliefs a way to exert their parental autonomy. As long as vaccination rates for the general population remain high and the number of exemptors at a minimum, society can tolerate the exemptions. However, the growing antivaccination movement, based on miscommunication and misperception of risk, may threaten the high vaccination rates that protect us all. Pediatricians and family physicians must find a way to enhance the quality of vaccine-risk communication and forge partnerships with parents about childhood vaccination in order to protect the entire population.

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POLICY FORUM

"You Can Pay Me Now, Or You Can Pay Me Later"

Geoffrey C. Williams, MD, PhD

Evidence clearly indicates that the health care system's and health care practitioners' greatest impact on quality and length of life comes from intervening to change health-related behavior.[1-5] Even the short-term costs of medical care are higher for patients who smoke, are physically inactive, or overeat than for those who have healthy lifestyles.[6] It is exactly like the oil filter commercial where the mechanic suggests it would be wiser to pay a few dollars now to change your oil filter, rather than paying thousands of dollars later for a new engine. Yet, few health care systems, insurers, or practitioners incorporate behavioral counseling services into everyday care.[7] Research into human motivation,[8] principles of clinical biomedical ethics,[9] and recommendations by the Centers for Disease Control and Prevention (CDC)[2, 4, 5] indicate the importance of supporting physicians and patients who take responsibility for improving behaviors in order to manage the current epidemic of behavior-related disease.

Behavioral Counseling by Physicians

The importance of behavioral counseling by physicians came into focus in 1993 when the CDC recognized that an estimated 50 percent of all deaths in the US are caused by unhealthy behaviors.[1] By 2001, the CDC had further clarified which of the many available preventive measures physicians should employ to have the greatest impact on improving quality and length of life for their patients.[2] Impact is a function of the efficacy of the intervention multiplied by the proportion of the at-risk population that receives the intervention. While brief behavioral counseling by physicians is efficacious,[2, 4] it tends to have lower efficacy than intensive interventions by behavioral specialists (eg, 10 percent versus 40 percent for tobacco-dependence counseling). However, physicians have much greater reach into the population than do behavioral specialists (eg, 70 percent versus 3 percent for tobacco-dependence counseling). Thus, brief physician counseling would have about 4 times the impact on the burden of disease caused by tobacco than behavior specialists alone. Effectiveness of physician behavioral counseling for secondary prevention in other diseases has also been established. For example, physician counseling for patients with diabetes was found effective in lowering cholesterol, achieving 2-year sustained weight loss, and encouraging smoking cessation.[10]

Brief behavioral counseling by physicians is further justified by its impact on extending individual patient's life expectancy and improving quality of life. Woolf argues that interventions for tobacco dependence (where the Number Needed to

Treat to prevent one death = 9), diet (where NNT=34), and physical activity (where NNT=16) have greater impact on reducing mortality than most if not all traditional medical interventions (eg, beta blockers after myocardial infarction where the NNT=120, or treatment of hypertension where the NNT=31).[5] Thus, brief behavioral counseling is important to the health of individual patients and to the health of the population. However, physicians provide these treatments to only about 20 percent of their patients.[2, 7]

Physicians need to have more than knowledge of the impact of an intervention to incorporate behavioral counseling into daily practice. They also need to have effective strategies that can be easily learned and applied in the busy practice setting. The US Preventive Services Task Force[4] recommends the 5As counseling as a brief behavior counseling model for physicians:

- **Assess:** assess behavioral health risks and patient goals.
- **Advise:** give clear and personalized behavior change advice.
- **Agree:** establish treatment goals collaboratively.
- **Assist:** aid the patient with behavioral counseling to achieve goals:
    - Provide positive interpersonal support for change,
    - Assist in skills building/problem solving,
    - Recruit social/environmental support,
    - Provide pharmacotherapy where appropriate.
- **Arrange:** schedule follow-up contacts.

The 5As model has a strong evidence base in tobacco and alcohol counseling. For the health of the population to improve, the 5As model needs to be adopted by physicians as the standard of care.[11]

While the potential impact of physician counseling for reducing behavior-related diseases underscores its importance, it is the principle of autonomy from biomedical ethics[9] and motivation theory[8] that mandates the adoption of brief behavioral counseling by physicians. Patients need to be fully informed in order to make autonomous health decisions. In turn, patients who are autonomously motivated are more likely to adopt and maintain the healthy behaviors that improve health over time.[12, 13] Physicians who fail to counsel patients about the health benefits of lifestyle change actually fail to fully inform them of their treatment options. For example, the current national guidelines for cholesterol[14] and stage 1 hypertension[15] indicate that physicians should recommend patients try 3 to 6 months of lifestyle change before adding medications to reach treatment goals. A modest weight loss of 10 lbs is expected to result in a reduction in 10 mm Hg in blood pressure and improve the patient's cholesterol.[15] The established impact of counseling and the ethical standard of informed decision making necessitate the widespread adoption of brief behavioral counseling by physicians.

Patients rely on physicians to inform them of their risks and interpret the absence of advice as tacit approval of their behavior. Even today, in spite of tobacco industry

warnings, many tobacco users remain poorly informed about the risks. Researchers report that more than 90 percent of smokers believe they are adequately informed of their risks.[16] However, 2 surveys found that almost half of smokers believe they are not at higher risk of heart disease or cancer than nonsmokers.[16, 17] Even simple advice from physicians (eg, saying "you should quit smoking") increases long-term abstinence for smokers in 2 meta-analyses by 30 to 70 percent.[3, 18] Smokers who are advised about abstinence by their physician report greater satisfaction with their care.[19]

Further, given that physician counseling is uniquely effective, and that patients rely on physicians to inform them about their health, failure to counsel has the consequence that physicians may unwittingly profit financially from the more expensive care that patients will require when they develop diseases caused by the unhealthy behaviors. By not providing counseling, physicians are falling below ethical standards of care because they are failing to support patient autonomy and informed decision making and may also may be profiting financially from their neglect.

Patient Accountability

Holding patients accountable for their behavior can lead to initiation and maintenance of behavior change if it is done in a manner that supports patient autonomy and competence.[8] If these attempts leave patients feeling controlled or manipulated, they will undermine patient motivation. Patient accountability is best accomplished by fully informing patients of their risks and the benefits of lifestyle change, eliciting their perspectives, providing advice and a clear rationale for change, and briefly helping them process their emotional reactions to the information. After patients have been informed, those who indicate a desire to change their lifestyle need competent support—a safe plan for change, skills training, problem solving, and follow-up.[3, 4]

Some argue that patients should be held accountable for the costs of the treatment of the diseases their behaviors cause. People quit smoking when the cost of cigarettes is increased through taxes.[20] Taxation is particularly effective in reducing tobacco use if the taxes collected are devoted to tobacco control.[20, 21] Similar arguments might be made for alcohol, and food intake, though lack of physical activity would be difficult to tax.

Holding patients accountable for copays for preventive services (eg, mammography or tobacco dependence counseling), however, has been shown to decrease the utilization of the services, as does making smokers pay out-of-pocket for medication and counseling that lead to successful treatment .[22, 23] Charging patients for trying to change their behavior may leave them feeling even more controlled, first by their addiction or inability to regulate their behavior and then by the system that might have helped them. Taxing tobacco and alcohol purchases seems likely to decrease the burden of diseases caused by these behaviors, whereas holding patients

accountable for paying for the treatment of their lifestyle disorders is likely to result in an increase in disease.

In a free society, where lifestyle is chosen and where physicians decide whether or not to intervene with their patients, evidence suggests that lifestyle behavioral counseling will be more likely to occur under systems that focus on supporting patient and physician autonomy and competence. With effective counseling available to prevent lifestyle-related diseases, it is no longer an acceptable standard of care for physicians or health care systems to fail to provide behavioral counseling, thereby passively allowing lifestyle-related diseases to develop, and then subsequently accepting payment for treatment of these diseases.

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The Ethics of Quarantine

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Recent events, specifically the SARS epidemic and concerns for the use of infectious agents for bioterrorism, have brought public health practice into prominence as an integral aspect of health care. For example, in the SARS epidemic, public health authorities in Canada relied upon quarantine for the first time in several generations. The use of quarantine raises several ethical concerns. Many people believe that quarantine constitutes an unwarranted diminution of personal liberty, whereas others see it as an integral aspect of communicable disease control. The purpose of this article is to discuss some of the ethical issues raised by quarantine and present requirements for its justification from an ethical perspective. This discussion draws on recent scholarship on public health ethics, particularly with respect to autonomy-limiting actions by public health authorities.

There is no doubt that communicable diseases pose threats to populations, and the simple administration of health care is insufficient to control the spread of communicable diseases. Over the past century, public health has developed a series of strategies to apply at a population level to control the spread of communicable diseases. The mode of transmission for most communicable diseases is well known, and hence population-based strategies, such as contact tracing and isolation, are frequently used for situations such as TB. However, there are circumstances when communicable diseases threaten populations, and a broader public health strategy may be required. Quarantine is but one component of communicable disease control. On its own, it is unlikely to be effective, and it is by no means the sole method of controlling an outbreak.

There are 2 independent ethical considerations to consider here: whether the concept of quarantine is justified ethically and whether it is effective. It is also important to make a clear distinction between quarantine and isolation. Quarantine refers to the separation of those exposed individuals who are not yet symptomatic for a period of time (usually the known incubation period of the suspected pathogen) to determine whether they will develop symptoms. Quarantine achieves 2 goals. First, it stops the chain of transmission because it is less possible to infect others if one is not in social circulation. Second, it allows the individuals under surveillance to be identified and directed toward appropriate care if they become symptomatic. This is more important in diseases where there is presymptomatic shedding of virus. Isolation, on the other hand, is keeping those who have symptoms from circulation in general populations.

Justification of quarantine and quarantine laws stems from a general moral obligation to prevent harm to (infection of) others if this can be done.[1] Most democracies have public health laws that do permit quarantine. Even though quarantine is a curtailment of civil liberties, it can be broadly justified if several criteria can be met.

In my analysis, published in the *Canadian Journal of Public Health*, I identified 4 principles that must be met in order for public health to contemplate an autonomy-limiting strategy.[2] First, the harm principle must be met. In other words, there should be clear and measurable harm to others should a disease or exposure go unchecked. For quarantine, this infection should be spread from person to person. In diseases that are infectious but cannot be spread from person to person, such as anthrax, quarantine cannot be justified.

Secondly, the proportionality, or least-restrictive-means, principle should be observed. This holds that public health authorities should use the least restrictive measures proportional to the goal of achieving disease control. This would indicate that quarantine be made voluntary before more restrictive means and sanctions such as mandatory orders or surveillance devices, home cameras, bracelets, or incarceration are contemplated. It is striking to note that in the Canadian SARS outbreak in the Greater Toronto area, approximately 30,000 persons were quarantined at some time. Toronto Public Health reports writing only 22 orders for mandatory detainment.[3] Even if the report is a tenfold underestimate, the remaining instances of voluntary quarantine constitute an impressive display of civic-mindedness.

Thirdly, reciprocity must be upheld. If society asks individuals to curtail their liberties for the good of others, society has a reciprocal obligation to assist them in the discharge of their obligations. That means providing individuals with adequate food and shelter and psychological support, accommodating them in their workplaces, and not discriminating against them. They should suffer no penalty on account of discharging their obligations to society.

Finally, there is the transparency principle. This holds that public health authorities have an obligation to communicate clearly the justification for their actions and allow for a process of appeal. If the above conditions can be met, there is a prima facie justification for the use of quarantine.

There are other frameworks for analysis of public health ethics. Nancy Kass[4] and James Childress,[5] for example, have recently published frameworks for the ethical appraisal of public health programs. In their frameworks, the effectiveness of an intervention plays an important role in justifying public health intervention. This is a double-edged sword, however. In an emergency such as SARS, it would be desirable to have knowledge that your actions, including that of quarantine, would be effective. But being constrained from action due to lack of evidence of effectiveness would severely hamper public health response—and quite possibly

lead to the further transmission of disease. As public health officers face these difficult dilemmas, it is important that they err on the side of public safety. It would be far better to defend oneself for unnecessary quarantine than to refrain from acting and expose individuals to a preventable disease, with subsequent morbidity and mortality. It should be noted that, despite controversies over quarantine, there is no clear or agreed-upon sense of what constitutes an effective quarantine.

This being said, it is important that there be a due process for quarantine. Barbera and colleagues have also addressed the issue of large-scale quarantine in the context of biological terrorism.[6] In their view, the effectiveness of quarantine is questionable and not justified on a mass basis. They indicate that quarantine actions have the capacity to cause harm. This is no doubt true. They do point out that there are several issues that need to be addressed, and they pose 3 major questions for a particular outbreak:

1. Do public health and medical analyses warrant the imposition of large-scale quarantine.
2. Are the implementation and maintenance of large-scale quarantine feasible?
3. Do the potential benefits of large-scale quarantine outweigh the possible adverse consequences?

Questions 1 and 2 are important and have been addressed in my framework. As to question 3, unfortunately, a priori, there may be very little information to work with. It is always hoped, of course, as a regulatory ideal, that more good than harm is done by intervention. I think that it is important for public health personnel to be mindful of this, particularly with respect to how people are supported. An effort should be made to minimize the long-term psychological impact and stigmatization of persons quarantined or otherwise affected.

In summary, then, quarantine is a blunt instrument to use in the control of infectious diseases. However, in some circumstances it is one of the only possible means of responding to an infectious disease threat. For example, early in the SARS outbreak in Toronto, when the disease showed rapid transmission to health care workers, the causative organism was unknown, as was the duration of communicability, mode of transmission, and incubation period. Many questions were unanswered. In this context of uncertainty, a prudent precautionary approach and the use of quarantine were likely justified. However, public health professionals must continually update their information in order to refine the exposure criteria, so that people are not needlessly quarantined. Hence, communication between public health professionals and clinicians is crucial. I also believe that physicians have a strong obligation to support public health in the control of communicable disease. Their actions in support of public health mandates are crucial in securing public credibility. Though many of these actions may be controversial, particularly when they begin to affect the livelihood of individuals, this is not an excuse for deviating from a control strategy. Transparency and communication are crucial in this regard.

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